Applicant: Shigeaki Kato et al. Attorney's Docket No.: 14875-054001 / C1-901PCT-US

Serial No.: 09/489,198 Filed: January 20, 2000

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#### **REMARKS**

Claims 8-9 are canceled without prejudice or disclaimer. Applicants reserve the right to pursue the canceled claims in one or more continuing applications.

Claims 10 and 11 have been amended to replace the term "gene" with "nucleic acid." New dependent claims 28-45 have been added. The amended and new claims are supported throughout the application, e.g., at page 13, lines 5-6 and 14-15; and page 16, lines 1-2. Upon entry of this amendment, claims 1-7 and 10-37 will be pending and claims 10, 11 and 28-45 will be under examination.

#### Rejections Under 35 U.S.C. §112, First Paragraph

#### Enablement

Claims 8-11 are rejected because, according to the Examiner,

the specification, while being enabling for a method for screening for a nucleic acid which encodes a polypeptide that converts an inactive form of vitamin D3 into an active form, does not reasonably provide enablement for a method for screening for a gene encoding a polypeptide that converts an inactive form of vitamin D3 to an active form, or a method for screening for a gene encoding an [sic, a] polypeptide that converts a ligand precursor into a ligand. (Office action, paragraph bridging pages 2-3.)

Claims 8 and 9 are canceled and claims 10 and 11 have been amended to recite screening a test "nucleic acid" that encodes a polypeptide rather than a test "gene" that encodes a polypeptide. This amendment is implicitly supported throughout the entire application. The present claims are thus commensurate with the Examiner's acknowledged scope of enablement. Accordingly, Applicants respectfully request that the rejection be withdrawn.

#### Written Description

Claims 8-11 are rejected as "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that that the inventor(s), at the time the application was filed, had possession of the claimed invention." The Examiner states:

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The specification discloses methods for screening for a nucleic acid which encodes a polypeptide that converts an inactive form of vitamin D3 into an active form wherein the nucleic acid is from human or mouse (i.e., SEQ ID NO: 1, 2 see page 16). However, detailed information regarding the structural and functional requirements of the gene encoding the polypeptide, as well as structural and functional requirements of the encoded polypeptide itself are lacking. (Office action, page 5.)

This rejection has been addressed, in part, by canceling claims 8 and 9 and amending claims 10 and 11 to recite screening a "test nucleic acid" that encodes a polypeptide rather than a "test gene" that encodes a polypeptide. However, the Examiner's implication that there is written description for a test nucleic acid from only human and mouse is respectfully traversed. For at least the following reasons, a skilled artisan would recognize that Applicants were in possession of the full scope of "test nucleic acids" to be screened in the claimed methods.

The present claims are directed to methods of <u>screening</u>. By definition, agents to be tested in a method of screening (in this case, test nucleic acids that encode a polypeptide) are not limited to one particular structure or one particular source. Indeed, screening assays are routinely claimed in terms of specific "test compounds" where no particular compounds are disclosed in the specification, because the invention lies in the steps of the method, <u>not</u> in the identity of the compounds that can be run through the screening assay. Here, even more than the usual detail is given in the claims, in that the compound to be tested must be <u>a nucleic acid</u> encoding a polypeptide.

A skilled artisan would understand that a "test nucleic acid encoding a polypeptide" describes, e.g., nucleic acids found in conventional, art-recognized, routinely available DNA libraries, such as cDNA or genomic libraries, from various sources. See, e.g., the specification at page 13, lines 21-22, which provides: "Genes are screened from cells or cDNA libraries prepared from mRNA isolated from tissues or the like, which are expected to express an objective gene." As stated in the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, paragraph 1 "Written Description" Requirement (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday, January 5, 2001) (hereinafter "the Guidelines") "[t]he absence of definitions or details for well-established terms or procedures should not be the basis of a rejection under 35 U.S.C. § 112, paragraph 1, for lack of adequate written description." Prior to the priority

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date, libraries of test nucleic acids were well-established and readily available from numerous sources, including human, mouse, bovine, cat, chicken, fruit fly, monkey, gorilla, orangutan, gibbon, rabbit, rat, and yeast (see ATCC Catalogue of Recombinant DNA Materials, 3<sup>rd</sup> edition, 1993, page 9, copy enclosed). Indeed, the *raison d'etre* of such DNA libraries is to provide test nucleic acids from numerous sources to be screened for various purposes, and this much would be understood by a skilled artisan faced with the term "test nucleic acid encoding a polypeptide". Given the ready availability of test nucleic acids from numerous species, Applicants' disclosure of mouse and human test nucleic acids is fairly representative of the full scope of the term. In fact, it would not have been necessary to name <u>any</u> species of animal in order to establish that Applicants were in possession of the full scope of the invention. Accordingly, the written description requirement is satisfied.

In light of the foregoing, Applicants respectfully request that the rejection be withdrawn. Enclosed is a Petition for Extension of Time along with the required fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date:

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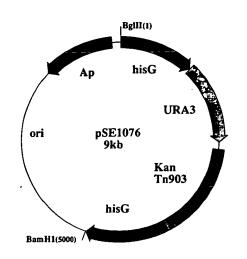
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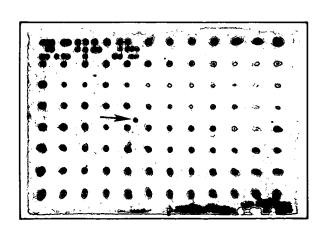
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# ATCC Catalogue of Recombinant DNA Materials\*

Third edition, 1993

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Pasteurella haemolytica   g   λΕΜΒΙΔ4: PhBam λΕΜΒΙΔ4   BamH1   C   9-25 kb   1Patent   40324   E   3208   deposit   ratberlain, 2-weeks-old   c   λgt11   λgt10   20 kb   RoStus   37476   E   1816   Rostus	orangutan lymphocyte		1.1011				0.2-1.8 kb				2331
Pasteurella haemolytica         g         λΕΜΒΙΔ4::PhSau         λ ΕΜΒΙΔ4         Sau3Al         P         9-24 kb         †Patent deposit deposit         40324         E         3208           rabbit liver rat brain, 2-weeks-old rat brain, 2-weeks-old rat brain, 12-weeks-old rat brain, 12-weeks-old, control	Pasteurella haemolytica			Charon 4A		Р	10-20 kb				185
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rat brain, 2-weeks-old rat brain, 12-weeks-old, cytoplasmic poly(A)+ RNA         c         λgt11					Haelli and Alui	P		HARDISON	37376	E	1806
Tat brain, 12-weeks-old, cytoplasmic poly(A)+ RNA   Saccharomyces cerevisiae   g   CEN BANK   YCp50   Sau3Al   P   10-20 kb   ROSE   37415   E   1818	rat brain, 2-weeks-old						0.5 kb average	GOLDIN	37477		
Saccharomyces cerevisiae   g   CEN BANK   YCp50   Sau3Al   P   10-20 kb   ROSE   37415   E   1821,   2119   Saccharomyces cerevisiae   g   AEMBL3A   Sau3Al   P   12-15 kb   ELLEDGE   77257   E   Saccharomyces cerevisiae   g   p366   Sau3Al   P   9-12 kb   HIETER   77162   E   Saccharomyces cerevisiae   g   pRS200   Sau3Al   P   8-10 kb   HIETER   77164   E   Saccharomyces cerevisiae   g   AYES-R   S   4-8 kb   ELLEDGE   77256   E   4639   Saccharomyces cerevisiae   g   YEp13   Sau3Al   P   5-20 kb   REED   37323   E   1809   Saccharomyces cerevisiae   g   pURSC1   pUR18   Sau3Al   P   3-10 kb   BARBET   77295   E   4594   White-handed gibbon lymphocyte   g   L1012   Character   Sau3Al   P   1.5-4.0 kb   BARBET   77296   E   4594   White-handed gibbon lymphocyte   g   L1012   Character   Sau3Al   P   1.5-4.0 kb   BARBET   77296   E   4594   White-handed gibbon lymphocyte   g   L1012   Character   Sau3Al   P   1.5-4.0 kb   BARBET   77296   E   4594   White-handed gibbon lymphocyte   g   L1012   Character   Sau3Al   P   1.5-4.0 kb   BARBET   77296   E   4594   White-handed gibbon lymphocyte   g   L1012   Character   Sau3Al   P   1.5-4.0 kb   BARBET   77296   E   4594   White-handed gibbon lymphocyte   g   L1012   Character   Sau3Al   P   1.5-4.0 kb   BARBET   77296   E   4594   White-handed gibbon lymphocyte   g   L1012   Character   Sau3Al   P   1.5-4.0 kb   BARBET   77296   E   4594   White-handed gibbon lymphocyte   g   L1012   Character   Sau3Al   P   1.5-4.0 kb   BARBET   77296   E   4594   White-handed gibbon lymphocyte   g   L1012   Character   Sau3Al   P   1.5-4.0 kb   BARBET   77296   E   4594   White-handed gibbon lymphocyte   g   L1012   Character   Sau3Al   P   1.5-4.0 kb   BARBET   77296   E   4594   White-handed gibbon lymphocyte   g   L1012   Character   Sau3Al   P   1.5-4.0 kb   BARBET   77296   E   4594   White-handed gibbon lymphocyte   g   L1012   Character   Sau3Al   P   1.5-4.0 kb   BARBET   77296   E   4594   White-handed gibbon lymphocyte   G   L1012   Character   Sau3Al   P   1.5-4.0 kb	rat brain, 12-weeks-old			. •				GOLDIN	37476		
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Saccharomyces cerevisiae         g         pRS200         Sau3AI         P         8-10 kb         HIETER         77164         E           Saccharomyces cerevisiae         g         λΥΕS-R         S         4-8 kb         ELLEDGE         77256         E         4639           Saccharomyces cerevisiae         g         YΕρ13         Sau3AI         P         5-20 kb         REED         37323         E         1809           Saccharomyces cerevisiae         g         pURSCI         pUR18         Sau3AI         P         3-10 kb         BARBET         77295         E         4594           Saccharomyces cerevisiae         g         pURSC2         pUR18         Sau3AI         P         1.5-4.0 kb         BARBET         77296         E         4594           white-handed gibbon lymphocyte         g         1.1012         Charce 44         5         D         CARR	Saccharomyces cerevisiae	g				-					
Saccharomyces cerevisiae   g	Saccharomyces cerevisiae	g		pRS200							
Saccharomyces cerevisiae         g         YRp7         Sau3Al         P         5-20 kb         REED         37323         E         1809           Saccharomyces cerevisiae         g         pURSCI         pURI8         Sau3Al         P         5-20 kb         REED         37324         E         1809           Saccharomyces cerevisiae         g         pURSC2         pURI8         Sau3Al         P         3-10 kb         BARBET.         77295         E         4594           White-handed gibbon lymphocyte         g         LI012         Chare 44         5-20 kb         REED         37323         E         1809           CARR         CARR         CARR         CARR         CARR         CARR	Saccharomyces cerevisiae	g			0445711						
Saccharomyces cerevisiae g pURSC1 pUR18 Sau3AI P 5-20 kb REED 37323 E 1809 Saccharomyces cerevisiae g pURSC2 pUR18 Sau3AI P 3-10 kb BARBET. 77295 E 4594  CARR  white-handed gibbon lymphocyte g L1012 Character Sau3AI P 1.5-4.0 kb BARBET. 77296 E 4594	Saccharomyces cerevisiae	g		YEp13	Sau3A1						
Saccharomyces cerevisiae  g pURSC2 pUR18  Sau3A1  P 3-10 kb  BARBET. 77295 E 4594  CARR  White-handed gibbon lymphocyte  g L1012  Chyce 44  Sau3A1  P 1.5-4.0 kb  BARBET. 77296 E 4594  CARR  CARR	Saccharomygan			YRp7		-					
Saccharomyces cerevisiae g pURSC2 pUR18 Sau3Al P 1.5-4.0 kb BARBET. 77296 E 4594 white-handed gibbon lymphocyte g L1012 Character S. D. CARR	Section yees cerevisiae	g	pURSCI			_				_	
white-handed gibbon lymphocyte g L1012 Character 5 De CARR	Saccharomyces caravisis					•			11295	E 4	1594
white-handed gibbon lymphocyte g 1.1012 Characada 5 pt CARR	complete cerevisiae	g	pURSC2	pUR18	Sau3A1	Р	1.5-4.0 kb		77207	_	
Charon 4A EcoRI P 10-20 kb SAKAKI *57742 P	white-handed gibbon lymphocus-		1.10.10						11290	E 4	1594
		5	LIV12	Charon 4A	Eco R I	P	10-20 kb		*57762	r .	0.6

Digest - C = complete (limit), P = partial, S = random shear.

Human chromosome-specific libraries deposited in connection with the ATCC/NIH Repository are described in the ATCC/ NIH Repository Catalogue of Human and Mouse DNA Probes and Libraries.

<sup>&</sup>lt;sup>2</sup> Insert — c = cDNA, g = genomic.

<sup>†</sup> This material is cited in a U.S. and/or other Patent or application and may not be used to infringe the patent claims.

<sup>\*</sup>The NIH requires the submission of a completed compliance agreement prior to shipment of any materials from the Repository. The form shown on page xi can be reproduced for this purpose.